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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,355	03/01/2002	Richard C. Boucher JR.	5470.250DV	3423
20792	7590	08/11/2004	EXAMINER	
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ART UNIT		PAPER NUMBER		
		1617		

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/087,355	BOUCHER, RICHARD C.
	Examiner Shengjun Wang	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 04 June 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 14,15,20,31-39,41-43 and 50-56 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 14,15,20,31-39,41-43 and 50-56 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

Receipt of applicants' amendments and remarks submitted June 4, 2004 is acknowledged.

Note the claims have been examined insofar as they read on elected invention and species.

### ***Claim Rejections 35 U.S.C. 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 14, 15, 20, 31-44 and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheele (U.S. Patent 5,863,563, of record) in view of Cropp and Glass (U.S. Patent 5,162,348, of record).

3. Scheele teaches a method for treating symptom of a patient who has pulmonary conditions, including cystic fibrosis, the method comprising causing the patient inhale a composition comprising alkali metal salts, such as potassium salt or sodium salts. Various anions may be employed, including bicarbonate. See, column 5, line 52 bridging column 6, line 18, and the claims.

4. Scheele does not teach expressly the employment of combination of salts, or the further employment of bronchodilator in the composition.

5. However, Cropp and Glass teach that bronchodilators are well known to be useful for treating cystic fibrosis, particularly administered in aerosolized forms. The well-known

bronchodilators include isoproterenol, metaproterenol. See, particularly, the abstract, table IV in Cropp and column 1, lines 44-51 in Glass. Glass further suggests that bronchodilators may be employed with other agents useful for treating cystic fibrosis.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ more than one of the known salts disclosed by Scheele in the therapeutical composition, or treating the patient with well-known bronchodilator before administering the instant composition.

A person of ordinary skill in the art would have been motivated to employ more than one of the known salts disclosed by Scheele in the therapeutical composition, or treating the patient with bronchodilator before administering the instant composition because all the salts disclosed by Scheele are known to be similarly useful in treating cystic fibrosis and it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for vcry the same purpose; idea of combining them flows logically from their having been individually taught in prior art; See In re Kerkhoven, 205 USPQ 1069. The combining treatment with bronchodilator is also obvious since bronchodilator is known to be useful for treating cystic fibrosis. The optimization of a result effective parameter, e.g., the method of administering two agents, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. The examiner assumes that claim 37, as amended, would still read on the elected potassium bicarbonate, absent an indication to the contrary.

***Response to the Arguments***

Applicants' amendments and remarks submitted June 4, 2004 have been fully considered, but are not persuasive for reasons discussed below.

Initially, it is noted that the claims have been examined insofar as they read on the elected invention and species. Applicants elected potassium carbonate as the salt or salts employed in the method in paper submitted October 10, 2002.

6. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teachings, suggestion, and motivation are found both in the cited references and in the knowledge generally available to one of ordinary skill in the art.

Particularly, the cited references teaches that each of the ingredients herein are individually known to be useful for treating pulmonary disease, such as cystic fibrosis, and the idea of combining them flows logically from their having been individually taught in prior art.

7. Applicants argue the cited references are incompatible with the claims, citing various functional description of the salt employed in the method. The arguments are moot to the issues in the rejections. Particularly, the claims have been examined insofar as they read on the elected invention and species, and applicants indicated in paper submitted October 10, 2002 that claims

1-44 read on elected salt(s), potassium bicarbonate. Absent indication to the contrary, it is reasonably presumed that potassium bicarbonate meet all the description.

8. Applicants further contend that instant claims recite “increase the volume of liquid,” which are different from Scheele’s teaching for increase pH. The examiner disagrees. First, since Scheele suggests a same method herein, i.e., inhale potassium bicarbonate to luminal surface, the recitation of intended function would make no difference. Further, Scheele teaches that by increasing pH, the method promotes the secretion of the cells. One of ordinary skill in the art would have reasonably expected that Scheele’s method would increase the volume of liquid on the airway.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SHENGJUN WANG  
PRIMARY EXAMINER  


Shengjun Wang

August 5, 2004